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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,157	08/07/2003	Hector F. DeLuca	960296.00104	3585
27114	7590	07/01/2004	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/636,157	DELUCA, HECTOR F.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### **Claims 1-12 are presented for Examination.**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Abele (U.S. Patent No. 5,631,289) evidenced by The American Heritage Dictionary of the English Language (1992).

Abele teaches the use of a quantity of calcium formate in the form of orally administrable composition for the prophylaxis and therapy of calcium-deficiency symptoms in animal (title, abstract, column 2, lines 19-23, lines 58-63, column 4, claim 1).

Abele teaches the resorption of calcium from calcium formate through the digestive tract is comparably effective with the calcium product heretofore known with out mucouse irritation in the digestive tract (column 2, lines 30-33).

The American Heritage Dictionary of the English Language teaches the term individual can be a single animal or a single human being.

Applicant's expression of increasing dietary calcium in an individual and improve calcium balance or retention would be inherent upon administration of Abele's calcium formulate composition in animal.

The American Heritage Dictionary of the English Language is used only as extrinsic evidence to explain the meaning of a term (individual) in the reference considered to be anticipatory.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slaga et al. (U.S. Patent No. 6,451,341B1).

Slaga et al. teach that dietary deficiencies of calcium are common and have been associated with accelerated bone loss resulting alveolar bone loss and accompanying oral health problems, osteoporosis and hypertension (column 15, lines 11-14).

Slaga et al. teach the formulation comprising calcium formate and vitamin D<sub>3</sub> (cholecalciferol) formulated in sustained-release tablet for dietary supplement

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for humans. (abstract, column 4, lines 34-40, column 5, lines 38-43, lines 50-51 and column 13, line 17).

Slaga et al. teach the preferred dosage of calcium formate range from about 40 to about 1000mg (0.04g-1g) once a day as required by claim 7 (column 5, line 30, lines 50-51, column 15, lines 15-16).

Slaga et al. teach vitamin D<sub>3</sub> (cholecalciferol) in the dosage of about 40 to about 4000 units aids the absorption of calcium and its primary role is mineralization of bones and teeth and the regulation of blood calcium levels (column 14, lines 29-36).

The reference do not expressly teach the formulation to improve calcium balance or retention, the amounts of calcium expressed in milliequivalents set forth in claim 2, and the gelatin capsule set forth in claim 4.

However, it would have been obvious to one of ordinary skill in the art to employ above formulation to improve calcium balance or retention because Slaga et al. teach that dietary deficiencies of calcium are common and have been associated with accelerated bone loss resulting alveolar bone loss and accompanying oral health problems, osteoporosis and hypertension. One of ordinary skill in the art would have been motivated with reasonable expectation of success to employ the formulation of Slaga to improve calcium balance retention since the formulation contains the active agents (calcium formate and vitamin D<sub>3</sub>), which are pertinent to calcium supplementation. Further, the amounts of calcium expressed in milliequivalents are obvious because the amounts of calcium formate utilized in above formulation encompass the milliequivalent

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conversion since they are within the range claimed by the Applicant. Moreover, the pharmaceutical forms, e.g., gelatin capsules, etc, set forth in claim 4 is deemed obvious because the benefit of calcium formate in sustained formulation tablet is well taught by the above reference hence, any variation to the selection of different oral dosage formulation i.e. gelatin capsule to meet a patient preference/compliance is well within the marketing of the pharmaceutical art.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slaga et al. (U.S. Patent No. 6,451,341B1) as applied to claims 1-4 and 6-12 above, and further in view of Drug Facts and Comparisons, 1997 Edition.

Slaga et al. as applied above.

Slaga do not teach the specific dosage regimen of calcium formate ingested in a first dose (before a mealtime) and second dose (after mealtime) set forth in claim 5.

Drug Facts and Comparisons, 1997 Edition teaches that calcium are generally dosed 2 to 4 times a day with meals or following meals to enhance absorption as a dietary supplement (see page 34, Patient Information and Administration and Dosage).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Slaga's daily regimen of calcium formate to twice a day dosing regimen generally around the mealtime because Drug Facts and Comparisons teaches calcium in general are dosed twice a day with meals or following meals to enhance absorption. One of ordinary skill in the

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art would have been motivated to modify Slaga's daily regimen of calcium formate in any sequence with mealtime twice a day to achieve the enhanced absorption of calcium as taught by the Drug Facts and Comparisons reference.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
June 15, 2004